

 **PACKAGE LEAFLET:**
Information for the patient

CINARIZINE

Tablets – 25 mg or 75 mg (Cinnarizine)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Cinarizine is and what it is used for
2. Before you take Cinarizine
3. How to take Cinarizine
4. Possible side effects
5. How to store Cinarizine
6. Further information

1. WHAT CINARIZINE IS AND WHAT IT IS USED FOR

Cinnarizine is a H1 receptor antagonist and a calcium channel blocker. Cinnarizine inhibits the transmission of calcium ions in the smooth muscle cells of arteries and causes vasodilatation. Cinnarizine is an effective therapeutic agent for the treatment of labyrinth disorders. It has anti-vasoconstrictor activity and therefore it is used to improve symptoms caused by poor cerebral and peripheral perfusion. Cinnarizine does not affect blood pressure and heart rate.

Cinarizine tablets are indicated in:

- cerebral atherosclerosis symptoms (dizziness, tinnitus, vascular headaches, memory disorders);
- consequences of head trauma;
- consequences of cerebrovascular accidents;
- migraine;
- peripheral vascular disorders (arteritis obliterans, Buerger's disease, Raynaud's disease, diabetes, acrocyanosis, frostbite);
- treatment of nausea and vertigo caused by Meniere's disease and other disorders of the labyrinth;
- prevention of motion sickness (travel by motor vehicle, boat, airplane).

2. BEFORE YOU TAKE CINARIZINE

Do not take Cinarizine if:

- you are sensitive (allergic) to cinnarizine or to any of the other ingredients of Cinarizine;
- you suffer from Parkinson;
- you have extrapyramidal motor system disorders;
- you suffer from porphyria.

Take special care with Cinarizine

Ask your doctor before you take Cinarizine if:

- you are pregnant or are planning to become pregnant, because it should not be used during pregnancy, especially during the first trimester;
- you have glaucoma;

- you have prostatic hypertrophy;
- you suffer from liver disease;
- you suffer from epilepsy (high doses may induce seizures in epileptic patients);
- you suffer from hypertension because Cinarizine is not recommended in these cases;
- it will be used in children because it is recommended to be used only for short periods.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Cinarizine.

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Cinarizine if you take any other medicine during treatment.

It is especially important that your doctor be aware of the fact that you are using or are being treated with:

- sedatives or tricyclic antidepressants (Cinarizine can increase their sedative effect);
- vasodilators and other antihypertensives (because Cinarizine acts synergistically when combined with them);
- antiemetic, domperidone (Cinarizine also acts synergistically with it).

Taking Cinarizine with food and drinks

Cinnarizine strengthens the sedative effect of alcohol and for this reason Cinarizine – tablets should not be taken simultaneously with alcohol.

Pregnancy and breastfeeding

Ask for the advice of a pharmacist or doctor before taking this drug. It is recommended to avoid the use of Cinarizine during pregnancy. Cinarizine should not be used during pregnancy, especially during the first trimester, so always consult your doctor before using Cinarizine during pregnancy.

Driving and using machines

You should be careful while driving or using machinery until you will see how Cinarizine affects you. Cinarizine may reduce the patient ability of driving or using machinery due to side effects caused from its administration, such as blurred vision.

Important information about some of the ingredients of Cinarizine

Cinarizine tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these medicines.

3. HOW TO TAKE CINARIZINE

Always take Cinarizine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you notice that Cinarizine effects are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with at least half glass of water.

The dosage of Cinarizine is individual. Below is presented a practical overview for its dosage.

Vestibular disorders:	75 mg, 1 – 2 times daily.
In ocular circulatory disorders:	75 mg, 2 – 3 times daily.
Peripheral vascular disorders:	75 mg, 2 – 3 times daily.
In motion sickness prevention:	
Adults and children over 12 years:	25 mg, 2 hours before travelling.
Children 5 - 12 years:	half the dose used for adults.
The maximum daily dose is 225 mg	

However, the dose may need to be increased or to be reduced. Your doctor will advise you accordingly.

If you take more Cinarizine

If you take more Cinarizine than you should, or if the children take it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Cinarizine

If you forget to take one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or higher) to make up a forgotten dose(s).

If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cinarizine can cause side effects, although not everybody gets them.

Sometimes they are serious, most of the time not. Do not get alarmed by this list of possible side effects. You may not get any of them.

Side effects that may occur are:

- at the beginning of treatment with cinnarizine may appear drowsiness;
- gastrointestinal disturbances (nausea, vomiting, diarrhoea and epigastric pain);
- headache;
- dry mouth;
- anorexia;
- blurred vision;
- allergic reactions;
- symptoms of incitement (paradoxical excitement);
- long-term medication can cause parkinsonism (in such cases treatment should be discontinued).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CINARIZINE

Keep out of the sight and reach of children!

Do not use Cinarizine after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Cinarizine contains

The active substance is cinnarizine.

Each tablet contains 25 mg cinnarizine.

The other ingredients: lactose, microcrystalline cellulose, talc, magnesium stearate and sodium starch glycolate.

Contents of the pack

Box with 30 tablets and box with 50 tablets.

Each tablet contains 75 mg cinnarizine.

The other ingredients: starch, lactose, microcrystalline cellulose, magnesium stearate, povidone, talc and sodium starch glycolate.

Contents of the pack:

Box with 50 tablets.

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



You should be careful during pregnancy



Content.



Warning.



Tablet shape.

Marketing authorisation holder (MAH) and manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in April 2015.

PAY ATTENTION, all the layers are visible.
If you have to print this document please
check or uncheck the specific layers.

 SPECIFICATION

 CROPING AREA 12 x 19 cm